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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/843,342	04/25/2001	Bruce L. Roberts	GA0211US	8525

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LEGAL DEPARTMENT
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EXAMINER	
VANDERVEGT, FRANCOIS P	
ART UNIT	PAPER NUMBER
1644	14

DATE MAILED: 09/09/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/843,342	Applicant(s) ROBERTS ET AL.
	Examiner F. Pierre VanderVegt	Art Unit 1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 March 2003 and 27 June 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-24* is/are pending in the application.

4a) Of the above claim(s) *1-6,12-21,23 and 24* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *7-11 and 22* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *See Continuation Sheet* .

Continuation of Attachment(s) 6). Other: Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence.

DETAILED ACTION

The Examiner in charge of your application in the USPTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to F. Pierre VanderVegt, Ph.D. in Art Unit 1644.

This application claims the benefit of the filing date of provisional application 60/200,.

Claims 1-24 are currently pending.

Claims **1-6 and 12-18 stand as withdrawn pursuant to the Restriction Requirement mailed July 1, 2002**.

Election/Restrictions

1. Applicant's election, responsive to the supplemental Restriction Requirement mailed June 2, 2003, of Group I, claims 7-11 and 22, as presented in Paper No. 13, filed June 27, 2003, is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 19-21, 23 and 24 are newly withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 13.

Claims **7-11 and 22 are the subject of examination** in the present Office Action.

In view of Applicant's amendment and response filed March 26, 2003, all previous grounds of rejection are withdrawn.

Specification

2. The disclosure is objected to because of the following informalities:

(a) This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence.

See, for example, page 47, line 27 and page 58, line 11 (CHPQXC) of the instant specification.

Applicant is reminded of the sequence rules that require a submission for all sequences of more than 9 nucleotides or 3 amino acids (see 37 CFR 1.821-1.825) and is also requested to carefully review the submitted specification for any and all sequences that require compliance with the rules.

Applicant is reminded to amend the specification accordingly.

(b) Page 45, line 15 of the specification recites "to an □v□3 integrin molecule..." It is not readily apparent what character the boxes are intended to denote. Applicant should amend the specification and clearly identify where antecedent basis for the correction is found in the specification.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 7-10 and 22 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 7 recites the limitation of a "self-assembling fusion polypeptide wherein said fusion polypeptide (i) is capable of forming a stable homomultimer." The limitation is not supported by the specification or claims as originally filed and constitutes new matter. Applicant asserts that the amendment to the claim is supported in original claim 4, page 17, lines 26-27 and page 36, lines 3-5. Review of the specification at page 36 indicates that only the oligomerization domains form homomultimers, not the entire fusion polypeptide. It is believed that Applicant intended to recite that the oligomerization domains form homomultimers and the claims are being treated thus. However, in its present state, **the recitation constitutes new matter** and must be corrected. Dependent claims 8-10 and 22 are included in this ground of rejection.

3. Claims 7-11 and 22 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus. (See Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001, especially page 1106 3rd column). A "representative number of species" means that the species that are adequately described are representative of the entire genus. Thus, when there is substantial variation within the genus, one must describe a sufficient variety of species to reflect the variation within the genus. MPEP 2163 II.A.3a.ii.

Claims 7-11 and 22 recite a polynucleotide, and vectors and cells comprising same, encoding a self-assembling fusion polypeptide capable of forming a stable homomultimer that comprises a T cell antigen presenting domain fused to an oligomerization domain without providing a physical structure for the polynucleotide. The genus of self-assembling polypeptides encoded by the claimed polynucleotides is therefore extremely large. Applicant has disclosed only MHC molecules as the antigen binding partner of the fusion construct and leucine zippers as the oligomerization domains which are "self-assembling" peptide segments that have a defined structure. Thus Applicant has disclosed only a limited number of "self-assembling polypeptides". These "self-assembling polypeptides" lack a common structure essential for their function and the claims do not require any particular structure be shared by the instant "self-assembling polypeptides comprising a T cell antigen presenting domain." It does not appear based upon the limited disclosure that Applicant was in possession of the necessary common attributes or features of the elements possessed by the members of the genus in view of the limited number of species disclosed and the extensive variation permitted within the genus of "self-assembling polypeptides comprising a T cell antigen presenting domain."

Consequently, Applicant was not in possession of the instant claimed invention. See Regents of the University of California v. Eli Lilly and Co. 119 F.3d 1559, 43 USPQ2d 1398 (Fed. Cir. 1997). Adequate written description of genetic material "'requires a precise definition, such as by structure, formula, chemical name, or physical properties,' not a mere wish or plan for obtaining the claimed chemical invention." Id. 43 USPQ2d at 1404 (quoting Fiers, 984 F.2d at 1171, 25 USPQ2d at 1606). The disclosure must allow one skilled in the art to visualize or recognize the identity of the subject matter of the claim. Id. 43 USPQ2d at 1406. A description of what the genetic material does, rather than of what it is, does not suffice. Id.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claim 10 recites the limitation "the polynucleotide of claim 47" in line 2. There is no antecedent basis for this limitation in the claim, as there is no claim 47 pending in the present application. It is believed that Applicant intended to recite --claim 7-- and the claim is being treated thus.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 7-10 and 22 are rejected under 35 U.S.C. 102(b) as being anticipated by Scott et al. (J. Exp. Medicine 183:2087-2095 (May 1996); U on form PTO-892).

Scott et al teaches a polynucleotide which encodes a fusion polypeptide comprising an extracellular domain of a murine IA Class II MHC alpha chain, which contains a T cell antigen presenting domain, and an oligomerization domain which can form a stable homomultimer. Scott teaches a second fusion polypeptide comprising an extracellular domain of a murine IA Class II MHC alpha chain, which contains a T cell antigen-presenting domain, and an oligomerization domain which can form a stable homomultimer, as recited in claim 7 (see entire article, especially the Summary). Scott teaches the gene delivery vehicle pRMHa3 vector comprising the polynucleotide (page 2088, first column in particular) [claim 8] and SC2 host cells comprising the polynucleotide [claim 9] and the polypeptide expressed from the polynucleotide (ibid) [claim 10]. Said fusion protein taught by Scott et al comprises a leucine zipper domain as the oligomerization domain as recited by claim 22 (see entire article, especially the Summary). The prior art anticipates the claimed invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are

such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Scott et al. (J. Exp. Medicine 183:2087-2095 (May 1996); U on form PTO-892) in view of US Patent No. 6,015,884 to Schneck et al (A on form PTO-892).

Scott has been discussed supra. Scott does not teach a recombinant system comprising a first polynucleotide encoding the fusion protein and a second polynucleotide encoding an epitope that binds specifically to the antigen binding domain.

The '884 patent teaches the covalent linkage of an epitope, or MHC peptide, to a soluble Class II heterodimer (see entire patent, especially Figure 1C) and that the epitope binds specifically into the binding groove of the antigen binding domain. Prior to linkage of the first nucleotide, encoding the fusion protein, and the second nucleotide, encoding the epitope, the first and second epitopes exist as separate entities in the recombinant system and satisfy the metes and bounds of the claim as written.

Accordingly, it would have been prima facie obvious to a person having ordinary skill in the art at the time the invention was made to combine the teachings of Scott regarding the manufacture of heterodimers of promiscuous MHC domains using linking domains with the teachings of the '884 patent regarding the covalent linkage of an MHC peptide to a soluble Class II heterodimer. One would have been motivated, with a reasonable expectation of success, by the need to produce large quantities of human MHC Class II heterodimers for the study of immune recognition (Scott, Abstract in particular), the teaching of Scott that some human Class II haplotypes are promiscuous in the formation of heterodimers in a manner similar to murine IA haplotypes which can be joined by leucine zippers (page 2087 in particular) in order to study the interaction of the heterodimer with the MHC binding peptide in solution, for example by X-ray crystallography (Scott, page 2094 in particular).

Conclusion

5. No claim is allowed.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to F. Pierre VanderVegt whose telephone number is (703) 305-4441. The examiner can normally be reached on M-Th 6:30-4:00; Alternate Fridays 6:30-3:00. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center number is (703) 872-9306.Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

F. Pierre VanderVegt, Ph.D.
Patent Examiner
September 8, 2003

PHILLIP GAMBEL, PH.D
PRIMARY EXAMINER
TC 1600
9/8/03

Application No.: 09/843,342

NOTICE TO COMPLY WITH REQUIREMENTS FOR PATENT APPLICATIONS CONTAINING NUCLEOTIDE SEQUENCE AND/OR AMINO ACID SEQUENCE DISCLOSURES

The nucleotide and/or amino acid sequence disclosure contained in this application does not comply with the requirements for such a disclosure as set forth in 37 C.F.R. 1.821 - 1.825 for the following reason(s):

☒ 1. This application clearly fails to comply with the requirements of 37 C.F.R. 1.821-1.825. Applicant's attention is directed to these regulations, published at 1114 OG 29, May 15, 1990 and at 55 FR 18230, May 1, 1990.

☐ 2. This application does not contain, as a separate part of the disclosure on paper copy, a "Sequence Listing" as required by 37 C.F.R. 1.821(c).

☐ 3. A copy of the "Sequence Listing" in computer readable form has not been submitted as required by 37 C.F.R. 1.821(e).

☐ 4. A copy of the "Sequence Listing" in computer readable form has been submitted. However, the content of the computer readable form does not comply with the requirements of 37 C.F.R. 1.822 and/or 1.823, as indicated on the attached copy of the marked -up "Raw Sequence Listing."

☐ 5. The computer readable form that has been filed with this application has been found to be damaged and/or unreadable as indicated on the attached CRF Diskette Problem Report. A Substitute computer readable form must be submitted as required by 37 C.F.R. 1.825(d).

☐ 6. The paper copy of the "Sequence Listing" is not the same as the computer readable from of the "Sequence Listing" as required by 37 C.F.R. 1.821(e).

☒ 7. Other: Sequence "CHPQXC" disclosed in the specification is not identified by a SEQ ID NO:

If sequences disclosed have not been assigned a sequence identifier,

Applicant Must Provide:

☒ An ~~initial or~~ substitute computer readable form (CRF) copy of the "Sequence Listing".

☒ An ~~initial or~~ substitute paper copy of the "Sequence Listing", as well as an amendment directing its entry into the specification.

☒ A statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter, as required by 37 C.F.R. 1.821(e) or 1.821(f) or 1.821(g) or 1.825(b) or 1.825(d).

For questions regarding compliance to these requirements, please contact:

For Rules Interpretation, call (703) 308-4216
For CRF Submission Help, call (703) 308-4212
For PatentIn software help, call (703) 308-6856

PLEASE RETURN A COPY OF THIS NOTICE WITH YOUR RESPONSE